



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 10/601,542 | 06/23/2003 | Christian Noe | WEB-7765 D | 7818 |
| 24131 | 7590 | 06/29/2006 | EXAMINER | |
| LERNER GREENBERG STEMER LLP | | | HUI, SAN MING R | |
| P O BOX 2480 | | | ART UNIT | PAPER NUMBER |
| HOLLYWOOD, FL 33022-2480 | | | 1617 | |

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/601,542 | | NOE ET AL. | |
| | Examiner | | Art Unit | |
| | San-ming Hui | | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6-23-03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-36 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,956,062 ('062) in view of US 4,353,922 ('922).

'062 teaches a compound similar to the herein claimed compound, when R' is cyclohexyl and R" is hydroxyl, as acetylcholine antagonists (See col. 1-2, especially col. 2, lines 35-38, also 54-56). The only difference being the compound of '062 misses the quaternary amino group. '062 also teaches the diastereoisomers as similarly effective and useful in the invention (See col. 1, lines 62-72).

'062 does not expressly teach the quaternary amino group and such compound be useful in treating asthma. '062 does not expressly teach the herein dosage forms. '062 does not expressly teach the herein claimed optical purity of the compounds.

'922 teaches a compound having the quaternary amino group and the only difference being the compound of '922 is having a bridged bicycle quaternary amino group, instead of pyrrolidinium compound (see the abstract). '922 also teaches the compound is an acetylcholine antagonists that is useful in treating asthma. Such compounds are administered through oral, parenteral or inhalation routes of administration (See col. 2, lines 32-35).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the compound of '062 to incorporate the pyrrolidinium moiety and employ such compound to the method of treating asthma. It would have been obvious to one of ordinary skill in the art at the time of invention to administer the compound in various dosage forms. It would have been obvious to one of ordinary skill in the art at the time of invention to formulate the herein claimed compound with the herein claimed purity.

One of ordinary skill in the art would have been motivated to modify the compound of '062 to incorporate the pyrrolidinium moiety and employ such compound to the method of treating asthma since both the pyrrolidinium or the quaternary amino and the pyrrolidine groups are useful as acetylcholine antagonists and exhibit anti-cholinergic activity, modify the compound of '062 to include the pyrrolidinium moiety and employ such compound to the method of treating asthma would be reasonably

Art Unit: 1617

expected to be useful and effective. One of ordinary skill in the art would have been motivated to administer the compound in various dosage forms, in the herein claimed purity, since formulating the compound into various dosage forms would be considered as simply selection of obvious alternatives, since the herein claimed dosage forms are considered merely conventional dosage forms, especially the herein claimed routes of administration are known to be useful in treating asthma. The skilled artisan would have also been motivated to incorporate the pharmaceutical composition in foam, dry powder or aerosol dosage forms. Note that the employment of dry powder and aerosol inhalers in treatment of asthma is widely known in the art. Furthermore, the intraconversion of dosage forms is within the skill of the artisan and therefore obvious. Furthermore, absent some difference in kind between the various isomers the skilled artisan would have seen each isomer as *prima facie* obvious (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)).

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax

Art Unit: 1617

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


San-ming Hui
Primary Examiner
Art Unit 1617